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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,434	01/07/2002	David Wallach	WALLACH=1D	4966

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EXAMINER

JIANG, DONG

ART UNIT PAPER NUMBER

1646

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/036,434

Applicant(s)

WALLACH ET AL.

Examiner

Dong Jiang

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-8 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-8 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED OFFICE ACTION

Applicant's amendment filed on 02 December 2003 is acknowledged and entered. Following the amendment, claims 5 and 9 are canceled.

Currently, claims 1-4, 6-8 and 10 are pending and under consideration.

Withdrawal of Objections and Rejections:

All objections and rejections of claims 5 and 9 are moot as the applicant has canceled the claims.

The obviousness-type double patenting rejection of claims 1-4, 6-8 and 10 as being unpatentable over claims 1 and 12 of U.S. Patent No. 5,512,544 is withdrawn in view of applicant's terminal disclaimer.

Objections and Rejections under 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 4, 7 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3, 4, 7 and 8 are indefinite because it is unclear what "non-proteolytic protein" is meant. It might mean that the protein cannot be digested by protease, which is not likely to be enabled, or alternatively, that the protein lacks protease activity. The metes and bounds of the claims, therefore, cannot be determined.

Rejections Over Prior Art:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6-8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seckinger et al. (J. Exp. Med., April 1, 1988, 167(4): 1151-6), in view of Dayer et al. (J. Exp. Med., 1985, 162: 2163-2168).

Seckinger discloses an inhibitory factor of TNF- α (TNF- α INH) identified in human urine, which molecular weight is 40-60 kD, and pI ranges 5.5-6.1, and has a specific TNF- α inhibitory activity when tested in a cytotoxicity assay, which was competitively overcome by increasing concentration of hTNF- α (the abstract, and page 1515, the first and the second paragraphs). Additionally, Seckinger teaches that the PGE2 production induced by TNF- α on human fibroblasts may well be inhibited by the TNF- α INH (page 1515, line 8 from the bottom). The description of Seckinger's TNF- α INH matches that of the TNF inhibitor of the present invention as both exist in human urine, both have similar molecular weight (40-60 kD vs. 40-80 kD), overlapping pI ranges (5.5-6.1 vs. 6-8), and both exhibit a specific TNF inhibitory activity, which can be competitively overcome by TNF- α . Therefore, Seckinger's TNF- α INH seems to be the same as the TNF inhibitor of the present invention in the absence of evidence to the contrary. Although the present disclosure provides limited sequence information of the protein, it, by itself, does not make the instant protein novel or distinct from Seckinger's TNF- α INH.

The primary reference does not mention explicitly to use such a TNF inhibitor for treating conditions wherein TNF is to be eliminated or antagonized in order to inhibit the cytotoxic effect of TNF.

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Dayer teaches that cachectin/TNF has been implicated both as the primary mediator or shock in gram-negative septicemia, and as the agent responsible for cachexia in chronic infectious disease states, thus playing a major role in the mammalian inflammatory responses (page 2163, the second paragraph). Additionally, Dayer teaches that cachectin/TNF also evokes the production of collagenase and PGE2 by synovial cells and dermal fibroblasts (page 2164, the first paragraph), and thus, it may represent the major mediator of this phenomenon in vivo (page 2166, the last paragraph), and that PGE2 is believed to be an important stimulus for the production of intracellular proteases, and is known to trigger bone resorption by osteoclasts in the course of inflammatory disease such as rheumatoid arthritis (page 2164, the first paragraph, and reference 19).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use the TNF- α INH taught by Seckinger for the treatment of conditions wherein TNF is negatively involved, and its effect need to be antagonized, such as those taught by Dayer. The person of ordinary skill in the art would have been motivated to do so in order to treat diseases, and reasonably would have expected success because Seckinger has demonstrated that TNF- α INH has a specific TNF- α inhibitory activity, and is able to inhibit the cytotoxic effect of TNF- α .

Conclusion:

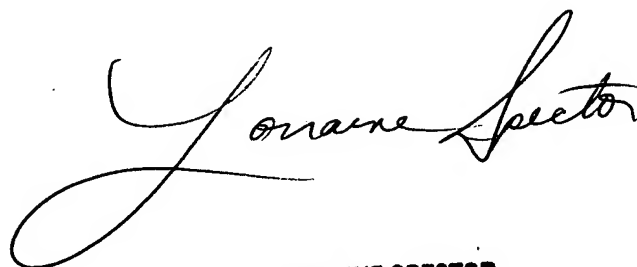
No claim is allowed.

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Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

A handwritten signature in black ink, reading "Lorraine Spector". The signature is written in a cursive, flowing style with a large initial "L".

**LORRAINE SPECTOR
PRIMARY EXAMINER**

Dong Jiang, Ph.D.
Patent Examiner
AU1646
2/18/04